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10/552,957	04/11/2008	Valerie Petay	033339/301225	1635

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EXAMINER
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TONGUE, LAKIA J

ART UNIT	PAPER NUMBER
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1645

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,957	<b>Applicant(s)</b> PETAY ET AL.	
	<b>Examiner</b> LAKIA J. TONGUE	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-25 have been amended. Claims 1-25 are currently pending and under examination.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on April 21, 2008 is in compliance with the provisions of 37 CFR 1.97 and has been considered. An initialed copy is attached hereto.

### ***Specification***

3. The use of multiple trademarks has been noted in this application, see for example pages 11-13. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Objections***

4. Claims 8, 9, 24 and 25 are objected to because of the following informalities: It is not clear as to whether or not Applicant intends to have claims 8, 9, 24 and 25 recite a Markush group. If said claims are indeed intended to be a Markush group, Applicant is required to amend the claims to include "consisting of language". For example, "wherein the aqueous substrate also comprises at least one additional ingredient

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selected from the group consisting of buffer salts, yeast extracts and cysteine hydrochloride. Appropriate correction is required.

5. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 is a substantial duplicate of claim 20.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-25 are drawn to an immunomodulatory product, obtained according to a method of preparation comprising the following steps: inoculation and incubation, under aerobic or anaerobic conditions and at a temperature of between approximately 30 and 40°C, of *Bifidobacterium* comprising at least the strain *Bifidobacterium breve* I-2219 in an aqueous substrate having a pH of between approximately 6 and 8 and comprising at least the following ingredients: i) lactoserum permeate, ii) a lactoserum protein

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hydrolyzate, iii) lactose, removal of the Bifidobacterium from the aqueous substrate; ultrafiltration of the aqueous substrate through filtration membranes having a cut-off threshold of between 100 and 300 kDa, so as to obtain a concentrated retentate; dehydration of the concentrated retentate, dissolution of the dehydrated retentate in a buffer; gel exclusion chromatography of the retentate solution, on a column having an exclusion threshold of 600 kDa; recovery of the excluded fraction at the end of the chromatography, which fraction constitutes the immunomodulatory product.

Because it is not clear that cell lines possessing the properties of ***Bifidobacterium breve* I-2219** are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required. Without a publicly available deposit of the above ***Bifidobacterium breve* I-2219**, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

Applicant's referral to the deposit of ***Bifidobacterium breve* I-2219** on page 2, lines 30-36 and page 3, lines 1-4 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the

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International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring: (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request; (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application; (c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and (d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the repository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain: 1) The name and address of the depository; 2) The name and address of the depositor; 3) The date of deposit; 4) The identity of the deposit and the accession number given by the depository; 5) The date of the viability test; 6) The procedures used to obtain a sample if test is not done by the depository; and 7) A statement that the deposit is capable of reproduction. As well as a statement that removes restrictions to provide access to this strain upon granting of a patent has not made, either in the instant Specification, nor in Applicant's Remarks.

One of the critical conditions of Deposit is defined in 37 CFR 1.808 requires that the deposit of biological material be made under two conditions: (A) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and (B) with one exception, that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent. Upon making this statement, the rejection under 35 USC 112, first paragraph will be withdrawn. This rejection can be obviated through perfection of the Deposit and amendment of the claims to clearly set forth the Deposited strains.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the ***Bifidobacterium breve* I-2219** described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1 is rendered vague and indefinite by the use of the terms "*Bifidobacterium breve* I-2219". The sole designation of bacterial strains by the internal designation I-2219 creates ambiguity in said claim. For example, the strain disclosed in this application could be designated by some other arbitrary means, or the assignment of the strain names could be arbitrarily changed to designate other strains. If either event occurs, one's ability to determine the metes and bounds of the claims would be



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impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204,208 (CCPA 1970). An amendment to the claim to specifically recite the depository and the accession number under which the claimed organism was deposited would satisfy this rejection.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 12/167,630 (US 2008/0268099 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims of the instant application are drawn to an immunomodulatory product, obtained

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according to a method of preparation comprising the following steps: inoculation and incubation, under aerobic or anaerobic conditions and at a temperature of between approximately 30 and 40°C, of *Bifidobacterium* comprising at least the strain *Bifidobacterium breve* I-2219 in an aqueous substrate having a pH of between approximately 6 and 8 and comprising at least the following ingredients: i) lactoserum permeate, ii) a lactoserum protein hydrolyzate, iii) lactose, removal of the *Bifidobacterium* from the aqueous substrate; ultrafiltration of the aqueous substrate through filtration membranes having a cut-off threshold of between 100 and 300 kDa, so as to obtain a concentrated retentate; dehydration of the concentrated retentate, dissolution of the dehydrated retentate in a buffer; gel exclusion chromatography of the retentate solution, on a column having an exclusion threshold of 600 kDa; recovery of the excluded fraction at the end of the chromatography, which fraction constitutes the immunomodulatory product. The Examiner is interpreting the obtained by recitations as product by process limitations and thus the claims are drawn to *Bifidobacterium* comprising at least the strain *Bifidobacterium breve* I-2219. Claim 6 of the co-pending application is drawn to the *Bifidobacterium breve* strain I-2219 deposited at the CNCM on May 31, 1999, thus meeting the limitation of the pending claims. Moreover, the disclosure of the co-pending application is obvious over the instant claims because it discloses that said deposited strain may be consumed as is or as a ready to eat product such as a milk product, an infant food product, or as food for subjects of all ages (see paragraphs 0028-0032 and 0035).

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Blareau et al. (U.S. 2008/0268099 A1; Filing date: 4/2/02).

The applied reference has a common Inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-25 are drawn to an immunomodulatory product, obtained according to a method of preparation comprising the following steps: inoculation and incubation, under aerobic or anaerobic conditions and at a temperature of between approximately 30 and 40°C, of *Bifidobacterium* comprising at least the strain *Bifidobacterium breve* I-2219 in an aqueous substrate having a pH of between approximately 6 and 8 and comprising at least the following ingredients: i) lactoserum permeate, ii) a lactoserum protein hydrolyzate, iii) lactose, removal of the *Bifidobacterium* from the aqueous substrate; ultrafiltration of the aqueous substrate through filtration membranes having a cut-off threshold of between 100 and 300 kDa, so as to obtain a concentrated retentate; dehydration of the concentrated retentate, dissolution of the dehydrated retentate in a buffer; gel exclusion chromatography of the retentate solution, on a column having an exclusion threshold of 600 kDa; recovery of the excluded fraction at the end of the chromatography, which fraction constitutes the immunomodulatory product.

Blareau et al. disclose the use of *Bifidobacterium breve* strain I-2219 (see paragraph 0020). Blareau et al. disclose that the product may be consumed as is or as a ready to eat product such as a milk product, an infant food product, or as food for subjects of all ages (see paragraphs 0028-0032 and 0035). Blareau et al. disclose the same strain as that which has been claimed, said *Bifidobacterium breve* strain I-2219 inherently comprises at least one peptide corresponding to SEQ ID NOs: 1, 2 and 3.

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With regard to claims 1-17, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Blareau et al. (U.S. Patent 7,410,653 B1; Filing date: 4/2/02).

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The applied reference has a common Inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-25 are drawn to an immunomodulatory product, obtained according to a method of preparation comprising the following steps: inoculation and incubation, under aerobic or anaerobic conditions and at a temperature of between approximately 30 and 40°C, of *Bifidobacterium* comprising at least the strain *Bifidobacterium breve* I-2219 in an aqueous substrate having a pH of between approximately 6 and 8 and comprising at least the following ingredients: i) lactoserum permeate, ii) a lactoserum protein hydrolyzate, iii) lactose, removal of the *Bifidobacterium* from the aqueous substrate; ultrafiltration of the aqueous substrate through filtration membranes having a cut-off threshold of between 100 and 300 kDa, so as to obtain a concentrated retentate; dehydration of the concentrated retentate, dissolution of the dehydrated retentate in a buffer; gel exclusion chromatography of the retentate solution, on a column having an exclusion threshold of 600 kDa; recovery of the excluded fraction at the end of the chromatography, which fraction constitutes the immunomodulatory product.

Blareau et al. disclose the use of *Bifidobacterium breve* strain I-2219 (see column 2, lines 42-47). Blareau et al. disclose that the product may be consumed as it is or as a ready to eat product (see column 2, lines 64-66). Moreover, Blareau et al. disclose

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that the strain is suitable for use as a milk product, infant food, or as food for subjects of all ages (see column 3, lines 34-36 and 39). Blareau et al. disclose the same strain as that which has been claimed, said *Bifidobacterium breve* strain I-2219 inherently comprises at least one peptide corresponding to SEQ ID NOs: 1, 2 and 3.

With regard to claims 1-17, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

11. Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Blareau et al. (WO 01/01785; Publication date: 1/11/01).

Please note this rejection is being made over WO 01/01785, which has not been translated, but the translated equivalent is US 7,410,653 B1, which is the national stage for the international application and has been applied above under 35 U.S.C. 102(e).

Claims 1-25 are drawn to an immunomodulatory product, obtained according to a method of preparation comprising the following steps: inoculation and incubation, under aerobic or anaerobic conditions and at a temperature of between approximately 30 and 40°C, of *Bifidobacterium* comprising at least the strain *Bifidobacterium breve* I-2219 in an aqueous substrate having a pH of between approximately 6 and 8 and comprising at least the following ingredients: i) lactoserum permeate, ii) a lactoserum protein hydrolyzate, iii) lactose, removal of the *Bifidobacterium* from the aqueous substrate; ultrafiltration of the aqueous substrate through filtration membranes having a cut-off threshold of between 100 and 300 kDa, so as to obtain a concentrated retentate; dehydration of the concentrated retentate, dissolution of the dehydrated retentate in a buffer; gel exclusion chromatography of the retentate solution, on a column having an exclusion threshold of 600 kDa; recovery of the excluded fraction at the end of the chromatography, which fraction constitutes the immunomodulatory product.

Blareau et al. disclose the use of *Bifidobacterium breve* strain I-2219 (see column 2, lines 42-47). Blareau et al. disclose that the product may be consumed as it is or as a ready to eat product (see column 2, lines 64-66). Moreover, Blareau et al. disclose that the strain is suitable for use as a milk product, infant food, or as food for subjects of all ages (see column 3, lines 34-36 and 39). Blareau et al. disclose the same strain as that which has been claimed, said *Bifidobacterium breve* strain I-2219 inherently comprises at least one peptide corresponding to SEQ ID NOs: 1, 2 and 3.

With regard to claims 1-17, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product



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itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

### ***Pertinent Prior Art***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Romond et al. (US. 2008/0038776 A1).

### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT  
4/28/10

/Robert B Mondesi/  
Supervisory Patent Examiner, Art Unit 1645